PRODUCT SPECIFICATION

Product PN *10496104*

Mod. 984

Rev. 02

Description Orange Serum Broth- Ampoules

Orange Serum Broth- Ampoules



PRODUCT DESCRIPTION	AMP Orange Serum 2ml, (50pk) Orange Serum Media: Organisms known to grow in single strength and concentrated juices are lactic acid and acetic acid bacteria and yeast. *Lactobacilli, Leuconostoc* and yeast have all been identified as spoilage organisms by numerous authors. Orange serum at pH 5.4 to 5.6 has been reported to yield maximum counts of all types of spoilage organisms in mixed cultures and in single culture comparison tests.
MANUFACTURER NAME	**GVS North America** **63 Community Drive** **Sanford, Me 04073** Phone: +1.866.736.1250 eMail: CustomerCareGVSLS@gvs.com - Website: www.gvs.com
INTENDED USE / APPLICATION	Orange Serum Broth is used to cultivate aciduric microorganisms associated with the spoilage of citrus products.
MATERIALS	**Media:** Orange Serum Broth **Color:** Dark amber nutrient liquid **Ampoules**: polypropylene **Regulatory Documentation Required:** ☐Biocompatibility according ISO 10993-1 ☐IMDS ☒Rohs, directive 2002/95/CE ☐BSE/TSE, directive 2003/32/ ☐DEHP plasticizer Free and latex free ☐Aging ☒Reach 1907/2006/CE (hazardous substances regulation) ☐Dir. 67/548/CE and Reg. 1272/2008/CE (medical sector dangerous substances) ☒Conflict minerals

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PRODUCT CHARACTERISTIC	**Dark amber colored liquid media dispensed in plastic ampoules.** **Physical:** **Ampoule Dimensions:** 57.9 mm x 8.4mm (at cap)/22 mm (at seal) **Volume/ampoule:** 2 - 2.4 ml **Incubation Temperature Range:** Organism dependent- *C. albicans* at 25°C ±2°C; *L. plantarum* at 35°C ±2°C **Storage temperature Range:** From 2°C to 8°C **Biological:** Product is sold sterilized. **Toxicity:** See SDS for further information. **Media Formulation:** Approximate formula* per liter of water Orange Serum 10.0 gm Yeast Extract 3.0 gm Pancreatic Digest of Casein 10.0 gm Dextrose 4.0 gm Dipotassium Phosphate 2.5 gm ** Adjusted and/or supplemented as required to meet performance requirements* *pH 5.6 ± 0.2*
INSTRUCTIONS **WARNINGS**	Product is temperature sensitive. Store at recommended temperature.
PRODUCT SHELF LIFE	12 months when stored properly
STERILIZATION	Product is sold sterilized

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PACKAGING AND LABELLING

Primary: 50 ampoules are placed in a labeled foil bag and sealed using a heat sealer.



CERTIFICATE OF COMPLIANCE

With each shipment, GVS NA will provide the CoC with item number, lot number and expiration date. The Quality management system is in compliance with ISO 9001.

VISUAL REQUIREMENTS

Visual acceptance requirements apply when inspected under below conditions:
Magnification: none
Light type: normal room lighting

	Acceptance Requirement		Sampling Plan
1	Color – Dark amber	all	100%
2	Ampoule appearance – no misshapen or leaking ampoules	none	

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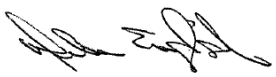
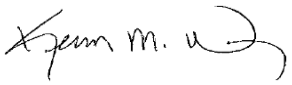
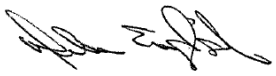
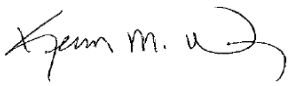
Description Orange Serum Broth- Ampoules

PERFORMANCE REQUIREMENTS

Acceptance Requirement			Sampling Plan
	Parameter	**Specification**	ISO 11133:2014
1	Recovery (Measured against control)	≥ 85%	ISO 11133:2014
2	Test Organism	*L. plantarum* ATCC 8014 *C. albicans* ATCC 10231	ISO 11133:2014
3	pH at 25°C	5.6 ± 0.2	ISO 11133:2014
4	Sterility	Zero Growth	ISO 11133:2014
5	Media Color	Dark Amber	ISO 11133:2014
6	Colony Color	Organism Dependent	ISO 11133:2014
7	Incubation	Incubate *L. plantarum* at 35°C ± 2°C for 48 hrs. *C. albicans* at 25°C ± 2°C for 48 Hours	ISO 11133:2014

This material specification describes the properties of product above indicated.
This document contains general requirements, material description, drawing references, defect specification, biological material requirements.

REVISIONS AND APPROVALS:

DATE	REV.	*REASON FOR CHANGE*	ISSUED AND CONTROLLED BY: (name /function and signature)	APPROVED BY: (name /function and signature)
11/7/18	0	Initial release	Debra English/Manager Biochemistry Applications 	Kevin Wrigley/Director, Quality 
7/28/2021	1	Update description, label, ampoule dimension & add media formulation	Debra English/Manager Biochemistry Applications 	Kevin Wrigley/Director, Quality 

CustomerApproval:

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Description **Orange Serum Broth- Ampoules**

We accept this material specification as a part of the agreed terms of delivery

Company name _____

Approved by: _____

(Name, Function) (Signature)

Date _____ _____

(Company stamp)

Please send back this document signed for approval. If we will not receive this specification signed, we consider the first order placed as implicit approval.